IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Christopher Batich et al.

Serial No. 09/965,740

Publication No. US 2002/0177828

Filed: 09/28/2001

For: Adsorbent Materials with Covalently Bonded, Nonleachable Polymeric

Antimicrobial Surfaces, and Methods for Preparation

Atty. Docket No. QMT1.1-CIP-US

Group Art Unit: 3761

Examiner: Catherine Anderson

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Dr. Rustom S. Kanga declares as follows:

Declarant

I am a consultant for Quick-Med Technologies, Inc. ("QMT") and make this statement in support of the patentability of U.S. patent application 09/965,740 (the "present application").

QMT is one of two assignees of the present application. The University of Florida Research Foundation is the other of the assignees of the present application.

Credentials

I received a Ph.D. degree in Polymer Chemistry from the University of Florida. My early research career focused on water-dispersible elastomeric photopolymers using anionic polymerization techniques. After five years, I moved to MacDermid Printing Solutions in 1995 where I became a Research Project Manager in the Plates Division. My research interest was in flexography while at MacDermid.

Currently, I am President and Founder of Xiper Innovations, Inc. Xiper was founded in 2005 and is a consulting firm offering research and product development services to corporations.

I have published scientific and business publications in journals such as Macromolecules, Chemistry of Materials, and SPE Conference. I am also the inventor on fourteen U.S. patents and more than twenty European and PCT patents and applications.

The attached CV further exemplifies my qualifications.

Introduction

My declaration is submitted to support the conclusion that the subject matter of the present claims of the above-identified patent application would not have been obvious to a person having ordinary skill in the art from the disclosures of U.S. Patent 5,783,502 ("Swanson") and European Patent 0493970 ("Sherba") cited by the Examiner's Action of November 16, 2007.

The Examiner has asserted that it would have been obvious to a person having ordinary skill in the art to prepare co-polymers from the monomers of Swanson and the monomers of Sherba which could be covalently bound to a substrate.

It is my opinion that it would not be possible to prepare such combination polymers because the monomers of Sherba lack appropriate functionality for the process as disclosed.

Discussion

I have reviewed the disclosures of Swanson and Sherba as well as the specification and the present claims of the above-identified patent application. The above-identified patent application exemplifies the use of polymers of diallyldimethylammonium chloride (DADMAC). When DADMAC is polymerized in the presence of a cerium catalyst, the main chain of the resulting polymer is comprised of only carbon-carbon and carbon-nitrogen bonds. When the catalytic polymerization is done in the presence of a substrate, covalent bonds are also formed between the main chain of the polymer and the substrate. Those bonds are primarily carbon-carbon bonds and are non-hydrolyzable.

The above-identified patent application also exemplifies the use of polymers of vinylbenzyltrimethylammonium chloride ("VBTAC"). Polymerization of VBTAC produces a structure wherein the polymer backbone is comprised of only carbon-carbon bonds. Both the bonds within the polymer backbone and the bonds with the substrate are similarly non-hydrolyzable.

Swanson discloses a process of polymerizing vinyl-containing monomers to form co-polymers in reactions catalyzed by a radical initiator such as AIBN. The process allows for the formation of co-polymers having pendant antiviral (ammonium) groups and latent reactive groups.

Swanson discloses co-polymers that are covalently bonded to the fabric surface via latent reactive groups pendant to the polymer chain. See col. 2, lines 33-48 and col. 4, lines 51-60. Formula 1 and Formula 2, at col. 5, illustrate the position of the latent reactive R¹ group in a pendant side chain.

Swanson discloses a separate process wherein the latent reactive groups present in the pre-formed co-polymers are covalently bound to a substrate via a photocatalyzed reaction at the latent reactive R¹ group. The pre-formed Swanson co-polymers are bound to the substrate via a reaction of the R¹ group in the pendant chain. There is no direct covalent bonding between the main chain of the polymer backbone and the substrate. In the reaction sequence below, I have exemplified a typical reaction of two representative monomers disclosed in the Swanson patent to form the co-polymer chain. The vinyl groups of the acrylamide monomers are reacted in the presence of a radical initiator (e.g. AIBN) to form the co-polymer.

In the example reaction above, the R¹ group represents a typical latent reactive group of Swanson which would subsequently be reacted to bond with a substrate. Note that both the latent reactive group and the antiviral (ammonium) group are not in the main chain of the polymer.

In contrast, the Sherba polymers are prepared by self-condensation of the monomers without any catalyst, at either room or elevated $(50-60^{\circ}\text{C})$ temperatures. The monomers are linked via carbon-nitrogen bonds via a self-condensation polymerization process wherein a sulfonate group is displaced to provide the site of linkage. The process of polymerization taught in Sherba allows for different monomers to be linked, provided they have the core displaceable sulfonate functionality.

As can be seen from the structure diagrams above, the polymers of Sherba have ammonium groups within the backbone of the polymer. These polymers are comprised of carbon-carbon and carbon-nitrogen covalent bonds. While the bonds within the polymer are non-hydrolyzable, there is no reactive functionality, such as a double bond, within the monomer or the polymer which would allow one to covalently attach either the monomer or the polymer to a substrate via the photocatalytic process disclosed by Swanson or the cerium catalyzed process taught by Applicants.

The Sherba monomers will not react with the Swanson monomers to form copolymers. In Sherba, the alkyl residue of the sulfonate from one monomer must
react with the tertiary amine function of a second monomer in order for the
polymerization to occur. The monomers of Swanson do not have a core displaceable
sulfonate group and would not polymerize, either with themselves or with the
Sherba monomers, under the conditions disclosed by Sherba.

The monomers of Sherba lack a vinyl or latent reactive group. Thus, it is not possible to polymerize the Sherba monomers with themselves nor covalently bond any resulting polymer to a substrate using either of the catalytic processes described by Swanson. Also, it is not possible to co-polymerize the Sherba monomers with the Swanson monomers to form combination polymers because there are no vinyl groups on the Sherba monomers to react with the vinyl groups of the Swanson monomers via the radical catalyzed process.

Swanson discloses a photochemical process to bind the polymers to the substrate. The processes require that the polymer have pendant side chains that have a latent reactive R¹ group such as an azide or aryl ketone. None of the possible Sherba polymers have such a latent reactive group. Because the Sherba polymers have no latent reactive groups, the Sherba polymers cannot be reacted under the conditions of Swanson to form covalent bonds with substrates. Sherba also does not disclose a process for covalently bonding polymers to a substrate.

Conclusions

As disclosed in Swanson, the covalent bonds between the polymer's pendant groups and the substrate would generally be non-hydrolyzable. However, the bonds between the pendant groups and the polymer backbone are hydrolyzable ester and/or amide bonds. Swanson does not disclose compositions wherein the covalent bonds are formed directly between the substrate and the polymer backbone, as claimed by Applicants.

It is my opinion that the polymers of Sherba could not be covalently bound to substrates via the processes taught by Swanson because the Sherba polymers lack the required latent reactive group for the photocatalytic process. I also believe that monomers of Sherba could not be reacted with the monomers of Swanson to produce co-polymers because the Sherba monomers lack vinyl functionalities for the

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catalytic process of Swanson. Nor could such co-polymers be produced via the method of Sherba because the Swanson monomers lack the required displaceable sulfonate functionality.

It is also my opinion that the monomers of Sherba could not be reacted via the process claimed by Applicants to form polymers because the Sherba monomers lack a vinyl functionality required for the process. It is my opinion that neither the Sherba monomers nor polymers could be bound to a substrate via the processes claimed by Applicants because both lack reactive vinyl functionalities for the process.

In summary, it is my belief that one of ordinary skill in the art would not be able to react the Swanson monomers and Sherba monomers to produce co-polymers that could be covalently bonded to a substrate via a catalyzed process as asserted by the Examiner

Verification

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Rustom S. Kange

April 15, 2008

Dr. Rustom S. Kanga

RUSTOM S. KANGA, PH.D.

 1760 N. Milford Creek Lane
 M: (404) 483-9180

 Marietta, GA 30008-8140
 W: (678) 229-6152

 rkanga@xiperinnovations.com
 F: (206) 222-2317

Rustom Kanga is the President and Founder of Kiper Innovations, Inc., a consulting firm offering Research and Product Development services to corporations. Dr. Kanga is a Research Scientist and Product Development professional with extensive knowledge in the Graphic Arts (Printing), Photopolymers, UV Cure, Polymer Chemistry and Specialty Coatings industries. He also has extensive experience in international business practices. He has a proven track record in innovation with 14 US and 20+ European and PCT patents and is conversant with all aspects of product development from concept to market. He brings a well-rounded background of corporate experience and educational credentials (Ph.D. in Polymer Chemistry and an MBA) to Kiper Innovations.

Prior to Xiper Innovations, Dr. Kanga was Research Project Manager in the Plates Division for MacDermid Printing Solutions. During his tenure there (1995-2005), he headed a number of critical research initiatives in Digital and In-the-Round (ITR) Flexography, identifying several key technologies for continued growth of the flexographic market and MacDermid's market share. This effort resulted in 9 US patents and several (5+) commercial products. He led a team of technicians, associates, and engineers, developing his staff and guiding them in both company and independent research projects. Dr. Kanga also served as liaison for the corporation's patent attorneys for intellectual property protection and development.

From 1990-1995, Dr. Kanga was affiliated with W. R. Grace & Company as Research Chemist, Designed Polymers Research, in its Washington Research Center, During this sitnt, he designed and developed several novel water-dispersible elastomeric photopolymers using anionic polymerization, which resulted in several patents. Earlier career experiences included a year-long assignment at AT&T Bell Laboratories as a post-dectoral Member of the Technical Staff. There he trained in microlithography, which laid the foundation for his subsequent work in photopolymer chemistry. His initial work helped pave commercialization of AT&T Bell Laboratories 'CAMP-6 photoresist.'

His international experience includes work in Europe, Asia Pacific, and South America. In addition to completing his undergraduate work in India, Dr. Kanga served as a Visiting Scientist at Johannes Gutenberg University in Mainz, Germany under a NATO grant. He has also collaborated with scientists in France, Switzerland, China and Japan on ongoing research projects. As part of his EMBA International Management Practices Curriculum he visited major companies in Japan and Argentina.

Dr. Kanga is the author of numerous scientific and business publications and white papers published in journals such as Macromolecules, Chemistry of Materials and SPE Conference etc.

Dr. Kanga's educational credentials include a Ph.D. in Polymer Chemistry from the University of Florida, an MBA (Executive Program) from Georgia State University, and a B.Sc. (Technology) in Chemical Technology from Bombay University's Department of Chemical Technology (UDCT),

More detailed lists of his Consulting Services and Patents follow:

CONSULTING PROFILE

PRINTING

- All aspects of Digital (DTP) Technologies for Flexography
- · Photopolymers for Flexographic Printing
- . ITR (In-the-Round) Technologies for Flexography

RADIATION CURE TECHNOLOGIES

- · UV Cure Technologies for Photopolymer Printing Plates
- · 100% Solids UV/EB Curable Inks and OPVs
- UV Cure Coatings/Inks for Low Energy Difficult-to-Adhere Substrates (e.g. Polyolefins)
- 100% Solids, UV Curable Anti-microbial Coatings for Various Substrates

IR ABLATIVE COATINGS

 IR Ablative Masks based on Carbon Black for Flexographic, Lithographic, and Gravure Applications

· Transparent IR Ablative Coatings for Laser Marking

COATINGS

- Water-Borne Specialty Coatings for Various Substrates
- · Water-Borne UV Curable Coatings for Wood
- Weather-proof Water-Oil Repellent Coatings for the Architectural and Anti-Graffiti Market NANOTECHNOLOGY
 - Metal Oxide Nanomaterials for Scratch and Abrasion Resistant Coatings for Glass, Metal, Wood, Plastic and other Substrates
 - Metal Oxide Nanomaterials for UV Attenuation and Protection of Various Substrates
 - · Nanocomposite Applications in Printing

TEXTILE COATINGS AND TREATMENTS

· Water and Oil Repellent Coatings / Treatments for Various Fabrics and Textiles

ADHESIVES

- Water-borne Polyurethane and Acrylic Dispersion Adhesives for Wood, Film Lamination, Fabric-Film Composites for the Graphic Arts
- UV Curable PSA for both Temporary Bond and Permanent Bond Applications

PATENTS (US)

- Processless Digitally Imaged Photopolymer Elements using Microspheres, US 6,989,220 (Issued: 1-24-2006)
- Printing Sleeve with an Integrated Printing Surface, US 6,966,259 (11-22-2005)
- Processless Digitally Imaged Printing Plate Using Microspheres, US 6.806.018 (10-19-2004)
- Laser Imaged Printing Plates, US 6,916,596 (7-12-2005), US 6,756,181 (6-29-2004), US 6,605,410 (8-12-2003)
- UV-absorbing Support Layers and Flexographic Printing Elements, US 6,413,699 (7-2 2002)
- Laser Imaged Printing Plate Comprising a Multi-layer Slip Film, US 6,367,381 (4-9-2002)
- Method Of Making Laser Imaged Printing Plates Utilizing Ultraviolet Absorbing Layer, US 5,925,500 (7-20-1999)
- Multiblock Copolymers for Flexographic Printing Plates, US 5,304,458 (4-19-1994)
- Photosensitive Elastomer Polymer Compositions for Flexographic Printing Plates, US 5,550,005 (8-27-1996), US 5,344,743 (9-6-1994), US 5,290,662 (3-1-1994), US 5,223,375 (6-29-1993)